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PATENT

A

Case Docket No.: 00,063

ASSISTANT COMMISSIONER FOR PATENTS
BOX PATENT APPLICATION FEE
Washington, D. C. 20231

Date: June 6, 2000



Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Roger P. Jackson

For: REMOVABLE MEDICAL IMPLANT CLOSURE FOR OPEN HEADED IMPLANTS

Enclosed are:

- ☒ Abstract of the Disclosure (1 page) and
☐ 19 Pages of Specification and Claims
☐ 2 Sheets of drawings
☒ Information Disclosure Statement
☒ Verified statements to establish small entity status under
 37 C.F.R. 1.9 and 37 C.F.R. 1.27
☒ The filing fee has been calculated as shown below:

FOR	NO. FILED	NO. EXTRA	RATE	SMALL ENTITY		RATE	OTHER THAN A SMALL ENTITY	
				FEE			FEE	
BASIC FEE	*****	*****	****	\$ 345	or	****	\$ 690	
TOTAL CLAIMS	13	- 20 = 0	x 9=	\$ 0	or	x18=	\$	
INDEP. CLAIMS	3	- 3 = 0	x39=	\$ 0	or	x78=	\$	
MULTIPLE DEPENDENT CLAIM PRESENTED	0		+130	\$ 0	or	+260=	\$	
TOTAL				\$ 345	or	TOTAL	\$	

☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 50-1253. A duplicate copy of this sheet is attached.

☒ Our check No. 1237 is also enclosed to cover, among other items, the above filing fee.

Respectfully submitted,

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VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
BY INVENTOR

Applicant: Roger P. Jackson

Serial No.:

Filed:

For: REMOVABLE MEDICAL IMPLANT CLOSURE FOR OPEN HEADED IMPLANTS

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the above-entitled invention described in:

- (x) the specification filed herewith.
- () application Serial No. _____, filed _____.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who, upon knowledge and belief, could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

Name of Concern: Not applicable

Address of Concern: Not applicable

I acknowledge my duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

5-23-00
Date

Roger P. Jackson
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PATENT

REMOVABLE MEDICAL IMPLANT CLOSURE

FOR OPEN HEADED IMPLANTS

Background of the Invention

1 The present invention is directed to a closure for use
2 in conjunction with medical implants that have open heads
3 for receiving rods and the like and, in particular, to such
4 a closure that includes a break-off installation head and a
5 second removal head.

6 Various medical implants that are especially used in
7 conjunction with spinal surgery include open heads that
8 receive rods and other elements of an overall implant
9 system. These implants include bone screws, hooks and
10 related parts that are variously used to produce an overall
11 implant system. The implant system, in turn, provides
12 support to a patient's spine to compensate for disease,
13 injury or congenital defects.

14 Open headed implants normally have a pair of spaced
15 arms that are positioned on opposite sides of a channel that
16 receives a rod or the like for securing the implant to the
17 rod. The open headed implants are often preferable in

1 certain situations where it is better to lay a rod or other
2 element into the head rather than thread a rod through a
3 closed head. For example, where a rod must join with a
4 large number of bone screws along a substantial length of
5 curved spine, it is extremely difficult, if not impossible,
6 to thread the rod through each of the bone screws and follow
7 the curvature of the spine at the same time. Consequently,
8 open headed elements are typically very important in use
9 with spinal implant systems. However, open headed implants
10 have to be effectively closed to capture the rod or rod-like
11 member and locked in order to secure the rod member in a
12 fixed position relative to the implant and further the
13 closure must be removable should it be necessary to
14 disassemble at least that portion of the overall implant
15 system for some reason.

16 Plug-like closures have been provided for open headed
17 implants in the prior art. Such prior art closures are
18 externally threaded and are screwed into mating threads on
19 the interior surfaces of the implant arms. Most of the
20 prior art plug like closures have had a fairly large profile
21 in that they extend substantially above the implant in order
22 to have sufficient structure to both install and remove the
23 plug or, alternatively, the implant is made taller. Both of

1 these alternatives are undesirable, since it is preferred to
2 have as low a profile as possible with respect to the
3 overall system in order to have a minimal impact on the
4 patient's body subsequent to installation. Furthermore,
5 many of the prior art devices cannot be sufficiently
6 tightened or torqued against the rod member so as to lock
7 the rod from both axial and rotational movement relative to
8 the implant. The various elements of the overall implant
9 system are relatively small and the body can exert
10 substantial forces on these elements, especially in
11 situations where greater than normal forces are applied,
12 such as accidents or the like. Slippage between the various
13 elements can result in failure of the overall system and
14 serious injury to a patient.

15 Consequently, it is desirable to be able to both lock
16 the rod member relative to the implant with the closure by
17 use of high torquing forces during installation with a
18 relatively low profile subsequent to installation and yet
19 still have sufficient structure and ability to remove the
20 closure should it be necessary at a later time.

1 Summary of the Invention

2 A closure is provided for an open headed medical
3 implant. The implant may be a bone screw, hook or other
4 element used in a spinal implant system for providing
5 support or reconstruction to the spine. The implant
6 includes a head having a pair of spaced arms with a channel
7 located therebetween. The channel receives a rod member
8 through the open end of the implant head.

9 The closure then is used to close the head subsequent
10 to the head receiving the rod member. In particular, the
11 arms of the head are internally threaded with a
12 discontinuous thread and the closure is externally threaded
13 so as to be screwable into the threads of the head. Once
14 the closure is threadably received in the head, the closure
15 acts to capture the rod member.

16 The closure also includes a breakaway driving or
17 installation head that has a polyhedral shaped external
18 surface that is sized and shaped to be received in a driving
19 socket of a first tool. The plug is torqued by the first
20 tool acting on the driving head until a predetermined torque
21 is achieved at which time, the driving head breaks away
22 along a break off region. The breaking away of the driving
23 head provides for a low profile. The closure is torqued to

1 a preselected torque by the driving head which may be on the
2 order of 100 inch pounds, so as to bias the closure against
3 the rod member so as to lock the rod member in the implant
4 against both relative axial and rotational movement
5 therebetween.

6 The closure further includes a removal head that has a
7 polyhedral cross section that is different in comparison to
8 the polyhedral cross section of the driving member, so that
9 a common tool cannot be accidentally used to drive both and
10 over-torque the closure upon installation. The removal head
11 mates with a second removal tool that allows for unscrewing
12 the closure from the implant for removal purposes. The
13 removal head is smaller in comparison to the installation
14 head.

15 16 Objects and Advantages of the Invention

17
18 Therefore, the objects of the present invention are to:
19 provide a closure for use in conjunction with open ended
20 medical implants that provides capture of a rod member,
21 locking of the rod member with respect to the medical
22 implant against both rotational and axial movement and
23 removal of the closure should removal be necessary; to

1 provide such a closure having a plug body that is sized and
2 shaped to be mateably received in threads of arms associated
3 with the medical implant; to provide such a closure having a
4 driving head that breaks away at a predetermined torque to
5 provide a comparatively low profile; to provide such a
6 closure having a smaller removal head that remains with the
7 closure subsequent to breakaway of the driving head; to
8 provide a removal head that has a different cross section
9 associated therewith in comparison to the driving head such
10 that a socket tool utilized for torquing the driving head
11 cannot be inadvertently engaged with the removal head to
12 over torque the closure upon installation; and to provide
13 such a closure and overall system which is relatively easy
14 to use, inexpensive to produce and especially well adapted
15 for the intended usage thereof.

16 Other objects and advantages of this invention will
17 become apparent from the following description taken in
18 conjunction with the accompanying drawings wherein are set
19 forth, by way of illustration and example, certain
20 embodiments of this invention.

21 The drawings constitute a part of this specification
22 and include exemplary embodiments of the present invention
23 and illustrate various objects and features thereof.

1 Brief Description of the Drawings

2
3 Figure 1 is an exploded and perspective view of an open
4 headed bone screw and closure therefore in accordance with
5 the present invention.

6 Figure 2 is a fragmentary side elevational view of the
7 bone screw and closure with the closure being installed in
8 the bone screw and being rotated by an installation tool.

9 Figure 3 is a fragmentary side elevational view of the
10 bone screw with the closure plug fully installed therein and
11 with the driving head of the closure broken away.

12 Figure 4 is a fragmentary top plan view of the bone
13 screw, rod and closure subsequent to installation.

14 Figure 5 is a fragmentary side elevational view of the
15 bone screw and closure illustrated with a closure removal
16 tool just prior to joining with the closure

17 Figure 6 is a fragmentary cross sectional view of the
18 bone screw, rod, closure and closure removal tool at the
19 initiation of removal of the closure from the bone screw.

20
21 Detailed Description of the Illustrated Embodiment

22 As required, detailed embodiments of the present
23 invention are disclosed herein; however, it is to be

1 understood that the disclosed embodiments are merely
2 exemplary of the invention, which may be embodied in various
3 forms. Therefore, specific structural and functional
4 details disclosed herein are not to be interpreted as
5 limiting, but merely as a basis for the claims and as a
6 representative basis for teaching one skilled in the art to
7 variously employ the present invention in virtually any
8 appropriately detailed structure.

9 The reference numeral 1 generally designates a closure
10 in accordance with the present invention. The closure 1 is
11 shown utilized in conjunction with a medical implant bone
12 screw 5 and rod 6 that are operably incorporated in an
13 overall spinal implant system for correcting deformities,
14 injuries, or defects to the spinal column of the patient.
15 In use the bone screw 5 is inserted into a vertebral body 8.

16 The bone screw 5 includes a shank 12 and an open head
17 13. The head 13 has a pair of spaced and generally parallel
18 arms 15 and 16 that form a channel 17 therebetween that is
19 open at the distal ends of the arms 15 and 16. The arms 15
20 and 16 each include radially inward or interior surfaces 20
21 and 21 that are threaded, but spaced and not continuous with
22 one another.

1 Although the closure 1 of the present invention is
2 illustrated with a bone screw 5 having an open head, it
3 foreseen that the closure 5 may be used in conjunction with
4 any type of medical implant having a similar type of open
5 head, including hooks and the like used in spinal surgery.

6 The rod 6 is an elongate, often curved, rod or elongate
7 rod-like member that generally extends between multiple bone
8 screws 5 of the type shown here or other elements of the
9 spinal system. It is also foreseen that the rod member 6
10 could be a connector between two laterally spaced elements
11 of the overall system and similar structures that are
12 elongate or have a rod-like portion that can be placed
13 within the channel 17. The illustrated rod member 6 is
14 circular in cross section and has a smooth external surface,
15 however in accordance with the invention it is foreseen that
16 rods having other types of cross section and having rough or
17 knurled external surfaces could be utilized.

18 The closure 1 includes a body 24 that is disc or plug
19 shaped with a circular horizontal cross section. The body
20 has a radially outward cylindrical shaped surface 26 that is
21 threaded with a thread that is mateable with the threads on
22 the interior surfaces 20 and 21 of the arms 15 and 16. The

1 body 24 is relatively thin having a thickness that is
2 substantially less than its diameter.

3 A driving or installation head 29 and a removal head 30
4 are also coaxially attached initially to the body 24. The
5 driving head 29 is secured to the body at a breakaway region
6 33 just above the removal head 30 and is designed to break
7 away from the remainder of the closure 1 subsequent to a
8 predetermined torque being applied to the driving head 29,
9 such as 100 inch pounds, during installation of the closure
10 1 into the bone screw 5. The driving head 29 broken away
11 from the body 24 is shown in Figure 3.

12 The driving head 29 has a cross section perpendicular
13 to its axis of rotation that is hexagonal and is formed by
14 six flat faces that are joined together in a hexagonal
15 pattern.

16 An installation tool 38 is provided for driving and
17 torquing the driving head 29. The installation tool 38
18 includes a gripable handle 39 that allows a user to rotate
19 the tool and a socket 40. The socket 40 is shaped and sized
20 to snugly receive the driving head 29, as is shown in Figure
21 2.

22 The closure body 24 has an upper surface 43 and a lower
23 surface 44. Located on the closure body upper surface 43 is

1 the removal head 30 at a location whereat it is coaxial with
2 the body 24, but positioned beneath the driving head 29 and
3 the breakaway region 33 so that the removal head 30 remains
4 with the body 24 when the driving head 29 is broken away. A
5 point 45 depends from the lower surface 44 of the body 24.

6 The illustrated removal head 30 has a square cross
7 section perpendicular to its axis of rotation. Preferably
8 the removal head 30 has a different cross section as
9 compared to the driving head 29 so that the installation
10 tool 38 cannot inadvertently grip the removal head 30 when
11 installing the closure 1 and thereby produce too much torque
12 by bypassing the torque limitation associated with the
13 breakoff driving head 29. This can be accomplished by
14 having the removal head 30 be either significantly larger or
15 smaller than the driving head 30 in cross section, while
16 retaining the same polyhedral shape, and/or by providing the
17 driving head 29 and removal head 30 with different
18 polyhedral shaped cross sections that are incompatible with
19 one another and especially providing the removal head with a
20 cross section that is incompatible with the socket 40 of the
21 installation tool 38. In the illustrated embodiment the
22 removal head 30 is square and smaller than the hexagonal
23 driving head.

1 Subsequent to installation it may be necessary to
2 remove the closure 1 for various reasons. When removal is
3 necessary, a removal tool 47 is utilized. The removal tool
4 47 includes a gripable handle 48 and a lower socket 49. The
5 cross section of the socket 49 is essentially identical to,
6 but the reverse of, the cross section of the removal tool
7 30, perpendicular to the axis of rotation thereof so that
8 the removal head 30 is snugly receivable in the socket 49.
9 This allows the socket 49 to mate with the removal head 30,
10 as is shown in Figure 6 to allow the closure 1 to be
11 unscrewed from the bone screw 5. Removal usually takes less
12 torque in comparison to installation, so the head 30 may be
13 smaller than the head 29.

14 Thus the installation tool 38 is utilized to install
15 the closure 1 in a bone screw 5 during which installation
16 the driving head 29 breaks from the body 24 of the closure 1
17 at a predetermined torque so as to tightly snug the closure
18 1 against the rod member 6 and lock the rod member 6 in
19 position relative to the bone screw 5. If removal of the
20 closure 1 is required, the removal tool 47 is utilized to
21 unscrew the closure body 24 using the removal head 30 from
22 the bone screw 5.

1 It is to be understood that while certain forms of the
2 present invention have been illustrated and described
3 herein, it is not to be limited to the specific forms or
4 arrangement of parts described and shown.

5

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. A closure for use in conjunction with a medical implant having an inward threaded surface; said closure comprising:
 - a) a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and shaped to be threadably mated with a threaded surface of an implant;
 - b) a driving head having a first cross section associated therewith perpendicular to the axis of rotation; and
 - c) a removal head having a second cross section associated therewith perpendicular to the axis of rotation with said secured cross section being different from said first cross section.
2. The closure according to Claim 1 wherein:

- a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when a predetermined torque is applied to the driving head.
3. The closure according to Claim 1 wherein:
- a) said removal head is axially centered and positional between said body and said driving head.
4. The closure according to Claim 1 wherein:
- a) said driving head cross section has a first polyhedral shape and said removal head cross section has a second polyhedral shape different from said first polyhedral shape to prevent an installation socket tool from inadvertently gripping both said driving head and said removal head during installation.
5. A medical implant system comprising:
- a) an open headed medical implant having a head formed by a pair of spaced interiorly threaded arms defining a channel therebetween sized and shaped to receive a rod member; and;

- b) a closure member including:
 - i. a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and shaped to be threadably mated with said threaded arms;
 - ii. a driving head having a first cross section associated therewith perpendicular to the axis of rotation; and
 - iii. a removal head having a second cross section associated therewith perpendicular to the axis of rotation with said second cross section being different in comparison to said first cross section.

- 6. The implant system according to Claim 5 wherein:
 - a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when a predetermined torque is applied to the driving head.
- 7. The implant system according to Claim 5 wherein:

- a) said removal head is axially centered and positional between said body and said driving head.
8. The implant system according to Claim 5 wherein:
- a) said driving head cross section has a first polyhedral shape and said removal head cross section has a second polyhedral shape different from said first polyhedral shape to prevent an installation socket tool from inadvertently gripping both said driving head and said removal head during installation.
9. A closure for use in conjunction with an open headed medical implant having a pair of interiorly threaded arms for receiving the closure; said closure comprising:
- a) a cylindrical shaped body with a radial outward threaded surface sized and shaped to be threadedly received between arms of such an open ended implant; said body having an axis of rotation;
 - b) a driving head axially aligned with and attached to said body and having a first gripable outer surface; and

- c) a removal head axially aligned with and attached to said body and having a second gripable outer surface; said first and second gripable outer surface being different in configuration so as to prevent a tool used with said first surface from also accidentally gripping said second surface.

10. The closure according to Claim 9 wherein:

- a) said driving head is attached to said body at a breakaway region that provides for said driving head to break from said body when a preselected torque is applied to said driving head.

11. The closure according to Claim 9 wherein:

- a) said driving head and said removal head have different shaped cross sections perpendicular to said axis of rotation.

12. The closure according to Claim 9 wherein:

- a) said driving head is larger in cross section in comparison to said removal head.

13. The closure according to Claim 9 wherein:

- a) each of said driving head and said removal head have a number of faces forming a

polyhedral cross section; said driving head
having a different number of faces in
comparison to said removal head.

Abstract of the Disclosure

A closure for use in conjunction with an open headed medical implant for capturing and locking a rod member in the implant comprises a radially outward threaded cylindrical body sized and shaped to be threadably received between two arms of a head of the implant. The closure also includes a driving head and a coaxial removal head. The driving head breaks away from the body at a predetermined torque leaving the removal head. The driving head and removal head are of sufficiently dissimilar shape to prevent a tool with a socket for gripping the driving head from inadvertently gripping the removal head during installation and over-torquing the closure.

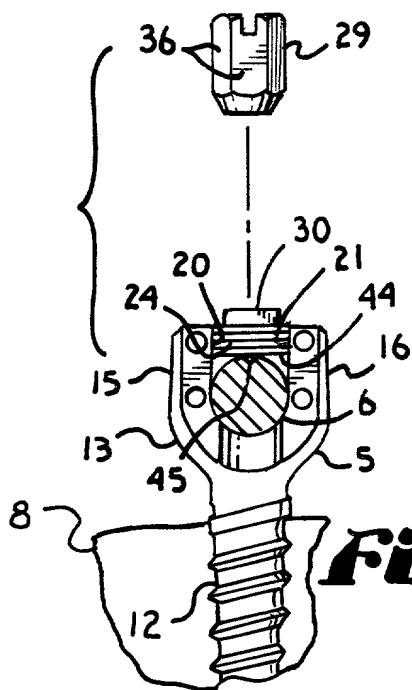


Fig. 3.

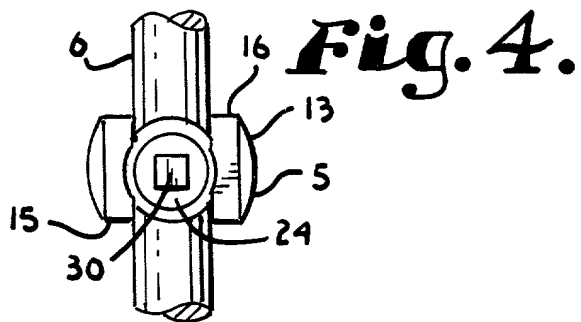


Fig. 5.

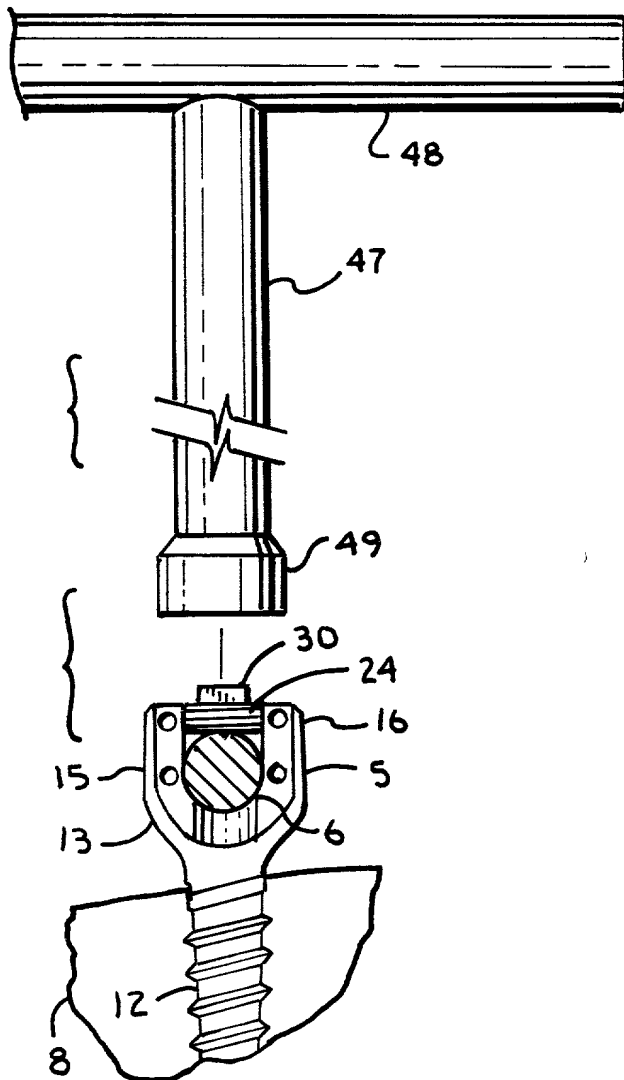
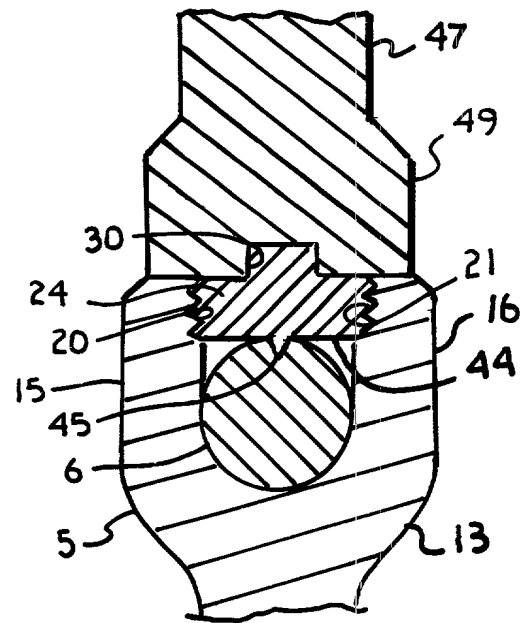


Fig. 6.



DECLARATION AND POWER OF ATTORNEY
FOR A PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled REMOVABLE MEDICAL IMPLANT CLOSURE FOR OPEN HEADED IMPLANTS, the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Sec. 1.56. (Under Sec. 1.56 information is material to patentability when it is not cumulative to information already of record before the Patent and Trademark Office with respect to the present application and it establishes either by itself or in combination with other information a prima facie case of unpatentability of a claim or it refutes or is inconsistent with a position taken in opposing an argument of unpatentability relied upon by the Patent and Trademark Office or in asserting an argument of patentability.

Under this section a prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.)

I hereby state that I do not know and do not believe that the invention was ever known or used in the United States of America before my invention thereof; that to the best of my knowledge and belief the invention has not been in public use or on sale in the United States of America more than one year prior to this application, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, or patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application; and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal

representatives or assigns.

I hereby appoint John C. McMahon, Reg. No. 29,415 and Malcolm A. Litman, Reg. No. 19,579, both members of the bar of the State of Missouri, whose postal address is PO Box 30069, Kansas City, Missouri 64112, telephone (816) 531-3470, as my attorneys, with full power of substitution, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent Office connected therewith in my behalf.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

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